No. 25-158
Consolidated with Nos. 25-572 and 25-573

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ALASKA COMMUNITY ACTION ON TOXICS, et al.,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
and LEE ZELDIN, in his official capacity as
Administrator of the United States Environmental Protection Agency,

Respondents.

On Petitions for Review of a Final Agency Action of the
United States Environmental Protection Agency
89 Fed. Reg. 102,773 (December 18, 2024)

PETITIONERS' OPENING BRIEF

October 17, 2025

Tosh Sagar
Earthjustice
1001 G St NW
Suite 1000
Washington, DC 20001
(202) 667-4500
tsagar@earthjustice.org

Michael Youhana
Earthjustice
48 Wall St., 15th Floor
New York, NY 10005
(212) 284-8033
myouhana@earthjustice.org

Counsel for Alaska Community Action on Toxics

Samantha Liskow
Environmental Defense Fund
257 Park Ave S
New York, NY 10010
(212) 616-1247
sliskow@edf.org

Counsel for Environmental Defense Fund

RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Ninth Circuit Rule 26.1-1, Petitioners Alaska Community Action on Toxics and Environmental Defense Fund state that they are non-profit corporations, have no parent corporation, and no publicly held corporation owns 10% or more of their stock.

DATED: October 17, 2025

/s/ Michael Youhana
Michael Youhana

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

Page number(s)

STATUTES

REGULATIONS

FEDERAL REGISTER NOTICES

LEGISLATIVE HISTORY

OTHER AUTHORITIES

INTRODUCTION

Alaska Community Action on Toxics and Environmental Defense Fund challenge a final regulation that unlawfully fast tracks the approval of some of the most dangerous chemicals—persistent, bioaccumulative, and toxic chemicals ("PBTs")—allowing them onto the market so long as they meet arbitrary criteria that do not protect health or the environment.

PBTs are among the worst of the worst: an insecticide known as DDT brought bald eagles to the brink of extinction; lead used in paint and gasoline continues to poison the brains of young children, decades after those products were banned; and today, so-called forever chemicals, per- and polyfluoroalkyl substances ("PFAS"), are found in municipal water systems, farmlands, and the bodies of 99% of adults. The danger of PBT chemicals lies in the fact that they persist and accumulate in the environment, making them incredibly difficult to clean up once they are released into the world.

In 2016, Congress amended the Toxic Substance Control Act ("TSCA")[1] to prevent such calamities from reoccurring. TSCA sets up a system of individualized review for every new chemical before it can be manufactured, which is designed to

[1] This acronym is typically pronounced "Tosca."

catch dangerous new chemicals and regulate them before they are introduced onto the market and cause harm.

However, in the challenged rulemaking, the Environmental Protection Agency ("EPA" or "Agency") thwarts Congress's intent by expressly exempting new PBT chemicals from the premanufacture review system for the first time ever. EPA's novel fast-track provision allows any new PBT chemical onto the market based on a cursory review, so long as the chemical meets arbitrary limits on production, release, or exposure that do not ensure the chemical is safe.

Fast tracking the approval of new PBTs is unlawful. TSCA only allows EPA to create such fast-track exemptions if the terms of the exemption regulation ensure, in advance, that new chemicals are safe—*i.e.* "will not present an unreasonable risk." 15 U.S.C. § 2604(h)(4). EPA has not met that standard here, as even EPA recognizes that the limits on production, releases, and exposures in its exemption regulations fail to ensure that new PBTs will not present unreasonable risk. That alone renders the rule unlawful. Furthermore, EPA's justification for its new rule—that there may be some hypothetical PBTs that do not release into the environment and cause no exposure—is arbitrary. It is doubtful that any such PBTs exist; indeed, EPA failed to identify a single one. And even if such PBTs did exist,

the rule sweeps far more broadly, allowing decidedly unsafe new PBTs to be manufactured.

Petitioners are non-profit organizations with members in fenceline communities near PBT-manufacturing facilities and in Alaska Native communities particularly at risk from PBTs. Petitioners seek to reduce their members' exposure to new PBTs in the air they breathe, the water they drink and fish in, the food they eat, and the products they use. Accordingly, Petitioners seek an order from this Court vacating the portion of EPA's new regulation that makes new PBTs eligible for fast-track review.

JURISDICTIONAL STATEMENT

The Courts of Appeals have exclusive jurisdiction to review rules issued under TSCA. 15 U.S.C. § 2618(a)(1)(A).

On December 18, 2024, EPA published the rule that is the subject of the consolidated petitions. ACAT-ER-004 (89 Fed. Reg. 102,773 (Dec. 18, 2024)) ("Final Rule"); *see also* 40 C.F.R. § 23.5 (specifying promulgation date for purposes of judicial review is two weeks from date of Federal Register publication). Petitioner Alaska Community Action on Toxics ("ACAT") timely petitioned this Court for review of the Final Rule on January 9, 2025. Petition for Review, No. 25-158, Dkt. No. 1.1; *see* 15 U.S.C. § 2618(a)(1)(A) (establishing 60-

day deadline to petition for review of TSCA rules). Venue is proper in this Circuit because ACAT's principal place of business is located within this Circuit. Miller Decl. ¶ 3; 15 U.S.C. § 2618(a)(1)(A).

On January 9, 2025, Petitioner Environmental Defense Fund ("EDF") timely petitioned the Second Circuit for review of the Final Rule, and the petition was subsequently transferred to this Court and consolidated with the other petitions challenging the Final Rule. Notice, No. 25-158, Dkt. No. 9.2; Consolidation Order, No. 25-158, Dkt. No. 9.3.

ISSUES PRESENTED

1. EPA found that new PBTs are inherently risky even if they comply with the terms of the low volume ("LVE") and low release and exposure ("LoREX") exemptions. Did EPA violate TSCA or act arbitrarily and capriciously by refusing to make new PBTs categorically ineligible for these exemptions to the more rigorous standard review process when EPA could not determine that new PBTs "will not present unreasonable risk" even when they comply with the terms of the exemption? 15 U.S.C. § 2604(h)(4).

2. EPA promulgated a new provision making every new PBT presumptively eligible for approval under the LVE and LoREX exemptions unless EPA affirmatively determines that the PBT will likely cause serious injury. 40

C.F.R. § 723.50(d)(2)(ii) ("PBT Fast-Track Provision" or "Fast-Track Provision"). Was EPA's promulgation of the PBT Fast-Track Provision in violation of TSCA and arbitrary and capricious because it makes PBTs eligible for the LVE and LoREX exemptions, even though the terms of the exemptions fail to ensure new PBTs "will not present an unreasonable risk" as required by 15 U.S.C. § 2604(h)(4)?

3. In a prior rulemaking, EPA made a category of chemicals ineligible for an exemption because EPA could not determine the category "will not present an unreasonable risk" under the terms of the exemption. Was EPA's promulgation of the Fast-Track Provision arbitrary and capricious because EPA failed to explain this departure from Agency precedent?

4. EPA sought to justify the PBT Fast-Track Provision by speculating that the LVE and LoREX exemptions could be used to safely manage new PBTs that result in zero releases and zero exposures. Was the promulgation of the Fast-Track Provision arbitrary and capricious because this hypothetical zero-release-zero-exposure rationale ignored Petitioners' contrary comments, was unsupported by evidence, and was unconnected to the regulatory text?

5. EPA claimed that the PBT Fast-Track Provision codified a 1999 policy governing the review of new PBTs. Was the Fast-Track Provision arbitrary

and capricious because EPA failed to respond to comments demonstrating that the Provision is inconsistent with the 1999 policy or to explain the Agency's departure from the policy?

STATUTES AND REGULATIONS

Pertinent statutes, regulations, and legislative history appear in the accompanying addendum.

STATEMENT OF THE CASE

I. Exposure to PBT Chemicals Endangers Human Health and the Environment.

Persistent, bioaccumulative, and toxic—or "PBT"—chemicals are amongst the most harmful and notorious chemicals. The pesticide DDT decimated bald eagle populations, bringing them to the brink of extinction, until it was banned. Polychlorinated Biphenyls ("PCBs") released by a General Electric plant over 50 years ago have contaminated a 200-mile stretch of the Hudson River, creating the largest Superfund site in the United States that continues to cause problems 20 years after cleanup began. Decades after bans on leaded gasoline and lead paint,

lead from those products remains in the environment, resulting in ongoing damage to the developing brains of young children.[2]

A. PBTs are more dangerous than other chemicals because of their persistence (P) and their bioaccumulative (B) properties.

What differentiates PBTs from other toxic chemicals is their persistence and potential to bioaccumulate. Persistence (P) means PBTs "remain in the environment for long periods of time." 84 Fed. Reg. 36,728, 36,731 (July 29, 2019). And bioaccumulation (B) means they "build up or concentrate in [the] body tissue" of people and other organisms exposed to them. *Id.*

As a result, EPA recognizes that PBTs are of special concern because: "(1) their persistence in the environment increases the likelihood of exposure of biological systems to those chemicals; [and] (2) their bioaccumulative potential increases the probability that they will move vertically through and become embedded in trophic chains"—*i.e.* food chains. ACAT-ER-248. Once a PBT

---

[2] EPA, *Endangered Species: Save Our Species Information – Bald Eagle*, https://www.epa.gov/endangered-species/endangered-species-save-our-species-information-bald-eagle (last updated Aug. 6, 2025); ACAT-ER-262 ("Prominent examples of PBT chemical substances include the insecticide DDT and polychlorinated biphenyls (PCBs)."); NOAA, *Hudson River*, https://darrp.noaa.gov/hazardous-waste/hudson-river (last updated Apr. 11, 2025); EPA, *Third Five-Year Review of the Upper Hudson River Cleanup* (Jan. 2025), https://www.epa.gov/system/files/documents/2025-01/hudson_final3rdfyr_factsheet_english_2.pdf; EPA, *Learn about Lead*, https://www.epa.gov/lead/learn-about-lead (last updated Sept. 9, 2025).

chemical is released into the environment, it can be dangerous even "at low concentrations, [because] the combination of persistence and bioconcentration in organisms can result in residues high enough to approach a toxic dose." ACAT-ER-267; *see* ACAT-ER-248 (similar). Indeed, because of these characteristics, PBTs "can cause adverse health and ecological consequences for . . . years to decades or more." EPA, *Economic Analysis for Final Regulation of Decabromodiphenyl ether (DecaBDE) Under TSCA Section 6(h)* at 1-1 (Dec. 16, 2020), https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0080-0641.

B. It is critical to identify and manage the risks of PBTs before they enter commerce.

PBT chemicals are ubiquitous in modern society, and past experience demonstrates that, once PBT chemicals enter into commerce, they are likely to cause environmental contamination and harm people for years, or even decades, with the harm often not being recognized until years after.

1. Once PBT chemicals enter commerce, they can cause releases and exposures throughout their lifecycle—from initial manufacture, to processing into other products, distribution in commerce, and use, through ultimate disposal.

When PBTs are manufactured or processed at industrial sites, they release into local water and air, and as a result will quickly reach the communities that immediately surround the sites. *See, e.g.,* Agency for Toxic Substances and Disease

Registry, *Toxicological Profile for Perfluoroalkyls* at 648, 650–51 (May 2021), https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf (summarizing documented groundwater and drinking water exposures of people living near chemical plants to a PBT PFAS); 84 Fed. Reg. at 36,740–41 (describing releases of PBT flame retardant from manufacturing and processing).

PBTs are also in widespread use in consumer products, resulting in exposure in the home. Brominated flame retardants are widely used in many household products—including televisions, computers, textiles, mattresses, and children's toys—which can then release these flame retardants into homes. 86 Fed. Reg. 880, 884–85 (Jan. 6, 2021); 84 Fed. Reg. at 36,734–35, 36,741. PFAS—known as "forever chemicals" because of how long they persist—are found in everyday household products like nonstick cookware and stain resistant furniture. EPA, *PFAS National Primary Drinking Water Regulation Fact Sheet* at 1 (Apr. 9, 2024), https://www.epa.gov/system/files/documents/2024-04/pfas-npdwr_fact-sheet_general_4.9.24v1.pdf.

Eventually, PBT-containing products reach the end of their useful life and have to be disposed of; and once sent to a landfill, recycler, or incinerator, they can cause significant environmental releases. *See* ACAT-ER-159; EPA, *Learn About Polychlorinated Biphenyls (PCBs)*, https://www.epa.gov/pcbs/learn-about-

polychlorinated-biphenyls (last updated Mar. 28, 2025) (discussing ongoing releases from landfills and incinerators); 84 Fed. Reg. at 36,740–41 (describing releases resulting from disposal of a PBT flame retardant).

2. These releases can lead to widespread environmental contamination and human exposure, which can cause harm long after a PBT is released. Repeated small releases of PBTs can build up over time, serving as a reservoir for the chemical and a source of ongoing exposure to plants, animals and humans, impacting whole ecosystems and the communities that live in and depend on these areas. And attempts at cleanup may fail, meaning people will continue to be exposed. As EPA recognizes: "Once PBT chemicals are released into the environment, they are often difficult or impossible to remediate." ACAT-ER-248 (emphasis added).

Thus, even as releases decrease—for example, because a chemical has been regulated or discontinued—harmful exposures can increase over time. *See* EPA, *Learn About Dioxin*, https://www.epa.gov/dioxin/learn-about-dioxin (last updated Jan. 18, 2025) ("In fact, a large part of current exposures to dioxins in the United States is due to releases that occurred decades ago."); *see also* EPA, *Exposure and Use Assessment of Five Persistent, Bioaccumulative, and Toxic Chemicals* at 109 (Dec. 2020), https://downloads.regulations.gov/EPA-HQ-OPPT-2021-0202-

0004/content.pdf (Environmental releases of decaBDE from ongoing use, recycling, and disposal of materials containing it "are likely to increase over time until the stock of available materials with decaBDE is depleted." (emphasis added)).

Although the use of PCBs was banned under TSCA almost 50 years ago, 15 U.S.C. § 2605(e) (1976), the chemical continues to release into the environment from existing products, landfill leaks, and waste incineration. EPA, *Learn About Polychlorinated Biphenyls (PCBs)*. For example, a portion of the Hudson River contaminated by PCBs from a General Electric plant is still in the process of being restored more than four decades after the area was listed as a Superfund site. NOAA, *Hudson River*. PCBs also persist throughout the Great Lakes and continue to present risks of exposure to people who might eat contaminated fish, such as lake trout or walleye. EPA, *Great Lakes Open Lakes Trend Monitoring Program: Polychlorinated Biphenyls (PCBs)*, https://www.epa.gov/great-lakes-monitoring/great-lakes-open-lakes-trend-monitoring-program-polychlorinated-biphenyls (last updated Nov. 27, 2024).

Difficulty remediating environmental releases of PBTs is not unique to PCBs. A now-shuttered lead-battery recycling plant in Los Angeles has required the cleanup of thousands of nearby homes, and the cleanup has been ongoing for

more than two decades. Cal. Dep't of Toxic Substances Control, *Exide Home*, https://dtsc.ca.gov/exide-home/(last visited Oct. 15, 2025). PFAS chemicals threaten the drinking water of at least 100 million U.S. residents, and "nearly all people in the U.S. have PFAS in their blood." EPA, *Biden-Harris Administration Finalizes First-Ever National Drinking Water Standard to Protect 100M People from PFAS Pollution* (Apr. 2024), https://www.epa.gov/newsreleases/biden-harris-administration-finalizes-first-ever-national-drinking-water-standard; Agency for Toxic Substances and Disease Registry, *Fast Facts: PFAS in the U.S. Population* (Nov. 12, 2024), https://www.atsdr.cdc.gov/pfas/data-research/facts-stats/index.html. One widely-used flame retardant has been detected in human blood, umbilical cord blood, and breast milk, as well as in fish, amphibians, birds, mammals, and invertebrates. EPA, *Exposure and Use Assessment of Five Persistent, Bioaccumulative, and Toxic Chemicals*, at 60–69, 72–88, 108–109.

Because PBTs are so ubiquitous, people are typically not exposed to a single PBT in isolation, "but rather to a complex mixture of multiple [PBTs]" and their combined effects may be more harmful than the sum of the individual chemicals. *See, e.g.,* Stockholm Convention on Persistent Organic Pollutants, *Report of the Persistent Organic Pollutants Review Committee on the Work of its Tenth Meeting; Addendum: Risk Profile on Decabromodiphenyl Ether*

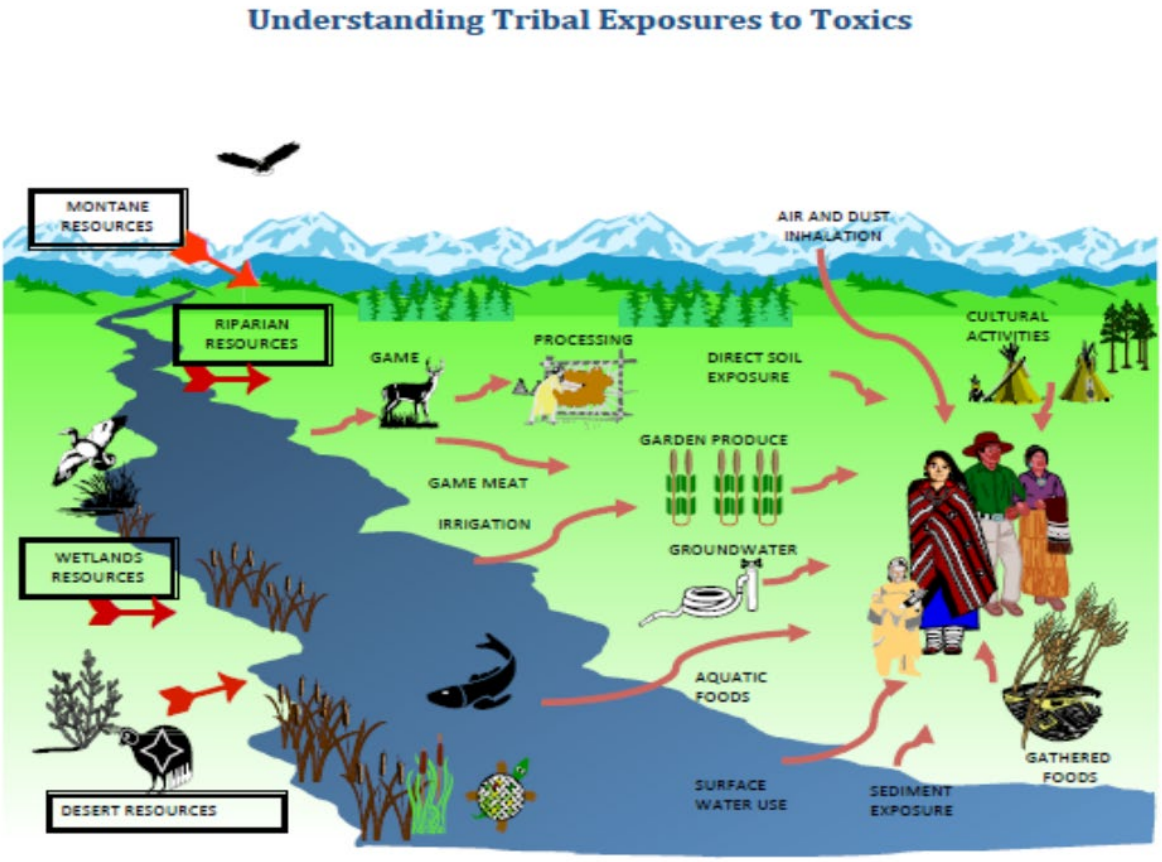
(Commercial Mixture, c-decaBDE) at 27–28 (Oct. 2014), https://chm.pops.int/TheConvention/POPsReviewCommittee/Reports/tabid/2301/ctl/Download/mid/7538/Default.aspx?id=17&ObjID=19072.

4. As demonstrated by the history of multiple PBTs—lead, PFAS, PCBs, and brominated flame retardants—the public, policy makers, and regulators often do not learn about the severe harm of PBT chemicals until years after the substances have exposed humans and the environment, with the widespread chemicals' toxic effects likely to continue for many years into the future. Thus, it is vital to appropriately regulate PBT chemicals before they get onto the market and then out into the world, when it is too late to prevent them from causing harm.

C. In order to protect Native Alaskans, it is necessary to manage the risks of new PBTs before they enter commerce.

Petitioner ACAT represents Native Alaskans, Indigenous people living in Alaska, whose health and way of life are threatened by widespread PBT contamination. *See generally* Miller Decl. PBTs manufactured and used in the mainland United States migrate thousands of miles on oceanic and atmospheric currents to Alaska in a process known as "global distillation." *Id.* ¶ 11. Once there, PBTs contaminate the traditional foods that Native Alaskans rely on for subsistence, including fish, marine mammals, and wild plants. *Id.* ¶¶ 11–13, 15; Waghiyi Decl. ¶ 4; Jemewouk Decl. ¶¶ 3–4. Whale and walrus meat relied upon by

some Native Alaskans have become so contaminated with PBTs that EPA recommends eating not more than one serving per month. Miller Decl. ¶ 15. These communities are uniquely exposed to PBTs through multiple additional pathways, as illustrated by EPA's tribal partnership group on toxic chemicals:



Nat'l Tribal Toxics Council, Understanding Tribal Exposures to Toxics at 8 (June 2015), https://nttc.sfo3.cdn.digitaloceanspaces.com/Docs/NTTC-Understanding_Tribal_Exposures_to_Toxics-2015-06-19.pdf.

As a result, Native Alaskans are among the world's most chemically contaminated populations, and are particularly overburdened by PBTs. Miller Decl. ¶ 15. PBTs are especially harmful to children and pregnant women in these communities, who have the some of the world's highest levels of PBT contamination in their blood and breast milk. *Id*. For example, women of child-bearing age in Alaska's Yukon-Kuskokwim Delta have the highest levels of toxic polybrominated diphenyl ethers of any population in the circumpolar Arctic. *Id*.

As one ACAT declarant states: "We cannot give up our traditional practices just to avoid exposure to POPs and other PBTs—it is our way of life as intended by our Creator. However, we are being contaminated without our consent." *See* Waghiyi Decl. ¶ 16. So long as PBTs are manufactured and released into the environment without proper regulation, these communities will continue to be contaminated without their consent. *Id*.

II. TSCA Establishes a System of Premanufacture Review to Prevent New Chemicals, Including New PBTs, from Causing Harm and Contamination.

A. Congress enacted TSCA to prevent chemical companies from experimenting on the public with dangerous new chemicals.

1. When Congress enacted TSCA in 1976, it sought to "assure that chemicals receive careful premarket scrutiny before they are manufactured," ending the status quo in which new chemicals "c[ould] be marketed without

notification of any governmental body and without any requirement that they be tested for safety." S. Rep. No. 94-698 at 3 (1976). To that end, Congress enacted a system of premanufacture review, recognizing that:

> [t]he most effective and efficient time to prevent unreasonable risks to public health or the environment is prior to first manufacture. It is at this point that the costs of regulation in terms of human suffering, jobs lost, wasted capital expenditures, and other costs are lowest.

Id. at 5. This premanufacture review system was meant to prevent the all-too-common occurrence in which a toxic chemical becomes ubiquitous before its toxicity is apparent. *See id.* at 4–5 (noting a number of such PBT chemicals). These premanufacture review provisions would prevent "the public or the environment [from being] used as a testing ground for the safety of these products." *Id.* at 3.

2. TSCA established a Standard Review Process, requiring chemical companies to apply to EPA before they could begin manufacturing a new chemical in the United States, by submitting a premanufacture notice ("Premanufacture Notice" or "PMN").[3] 15 U.S.C. § 2604(a)(1) (1976). EPA was required to review each Premanufacture Notice to determine the risk posed by the new chemical and to regulate it as necessary—up to and including blocking market access—to

[3] Petitioners refer to the process for reviewing Premanufacture Notices as "the Standard Review Process" for simplicity.

prevent potential harm to human health or the environment. *Id*. § 2604(a), (e), (f) (1976).

The Premanufacture Notice had to include, among numerous categories of information, a description of reasonably ascertainable data relating to the new chemical's health and environmental effects. *Id.* § 2604(b), (d) (1976). EPA had 90 days to complete its review of the Premanufacture Notice, but could extend the review period by another 90 days "for good cause." *Id*. § 2604(a), (b), (c) (1976). However, if EPA failed to take action on an application within the review period, the manufacturer was free to commence manufacture. *Id*. § 2604(g) (1976).

3. Congress recognized that there might not be enough information about a new chemical to make an accurate and "reasoned" evaluation of how much risk it poses. *Id*. § 2604(e)(1)(A)(i) (1976). Precisely because new chemicals are new, there might not be "[]sufficient" information about their health effects, *id.,* for example, because no studies have been conducted. In situations where information is lacking, a new chemical "may present an unreasonable risk," and Congress authorized EPA to: (1) issue an order to regulate the new chemical; and (2) require more testing by the applicant to enable EPA "to evaluate the health and environmental effects of [the] chemical." *Id.* § 2604(e)(1)(A), (2)(D) (1976).

B. TSCA established a high bar for EPA to exempt a category of chemicals from the standard premanufacture review process.

As relevant here, Congress authorized EPA to issue "rule[s]" that create exemptions from the Standard Review Process, and these exemption rules may cover a category of chemicals.[4] *Id.* §§ 2604(h)(4), 2625(c) (1976) (authorizing regulation by "category"). "[U]pon application and by rule" EPA may exempt a category of chemicals from the Standard Review Process if EPA determines the terms of the exemption ensure the category "will not present an unreasonable risk of injury to health or the environment." *Id.* § 2604(h)(4) (1976) (emphasis added).

When creating or modifying an exemption rule, EPA must find that the category of "new chemical substances eligible for the exemptions will not present an unreasonable risk . . . under the terms of the exemption[]." 60 Fed. Reg. 16,336, 16,345 (Mar. 29, 1995) (describing statutory test for exempting a category of chemicals). In other words, the terms of an exemption rule must create safeguards sufficient for EPA to determine, in advance, that a category of new chemicals will not present unreasonable risk. *Id.*

[4] TSCA established a limited set of statutory exemptions from the Standard Review Process as well. *See, e.g.,* 15 U.S.C. § 2604(h)(1) (1976) (test marketing exemption), § 2604(h)(3) (1976) (research and development exemption).

That is a high bar. EPA may create an exemption with less rigorous, expedited review procedures, but only if the Agency is certain that the exemption rule contains substantive limits that will keep people and the environment safe from a chemical approved under the exemption. If EPA cannot make this determination, it cannot create an exemption and chemicals must instead go through the Standard Review Process, where they will receive comprehensive, individualized review and regulation, if warranted. That fulfills TSCA's overarching purpose to "prevent the general environment from becoming the laboratory in which harmful effects of chemicals are discovered." *Dow Chem. Co. v. EPA*, 605 F.2d 673, 676 (3d Cir. 1979).

C. EPA created the LVE and LoREX Exemption rules to fast track the approval of new chemicals if specified limits on production, release, and exposure are met.

1. Following TSCA's enactment, EPA created the Low Volume Exemption ("LVE") and Low Release and Exposure Exemption ("LoREX") (together, the "Exemptions"). These Exemptions allow EPA to fast track the approval of new chemicals that meet specific production, release, or exposure criteria. 50 Fed. Reg. 16,477, 16,478 (Apr. 26, 1985); 60 Fed. Reg. at 16,336–38.

A new chemical is eligible for the LVE if it is "manufactured in quantities of 10,000 kilograms or less per year." 40 C.F.R. § 723.50(c)(1) (1995). A new

chemical is eligible for the LoREX if it meets criteria relating to release and exposure, such as: no dermal exposure; no inhalation exposure (except from certain air releases from incineration); and drinking water exposure and surface water concentrations under specified thresholds. *Id.* § 723.50(c)(2) (1995).

Under these Exemptions, a chemical manufacturer submits a "notice[]" (*i.e.* an application) to EPA before manufacturing a new chemical. *Id.* § 723.50(a)(2) (1995). The Agency then has just 30 days to review the application and determine whether the application meets the term of an Exemption, rather than the full 90-to-180-day timeframe in the Standard Review Process. *See id.* § 723.50(g)(1) (1995).[5]

2. As EPA recognizes, the 30-day review under the Exemptions is less "detailed and comprehensive" than the 90-to-180-day review for the Standard Review Process. ACAT-ER-006; *see also* ACAT-ER-016. Additionally, unlike the Standard Review Process, EPA does not "require testing or impose additional restrictions [by order]" for a chemical approved under the Exemptions. *Id.* Together, those deficiencies can make it difficult to "address . . . uncertainties" regarding the risk of a particular a new chemical. *Id.*

[5] The relevant limits on production volumes, releases, and exposures, as well as the 30-day length of the review period, remain unchanged even after issuance of the challenged Final Rule. *Compare* 40 C.F.R. § 723.50 (1995) *with* 40 C.F.R. § 723.50.

3. The chemical industry uses the Exemptions to avoid the Standard Review Process in order to get toxic chemicals quickly approved by EPA. For example, chemical industry attorneys have stated that obtaining an exemption is an "attractive option for high-toxicity substances," because "[i]f submitted as a [Premanufacture Notice], the same substance might well wind up being regulated" by EPA. Keller & Heckman LLP, *The Constantly Pending PMN: Low Volume Exemption Applications Are Living Documents*, Martindale (Mar. 16, 2011), https://www.martindale.com/chemicals/article_Keller-Heckman-LLP_1255440.htm. The industry also sees "advantage[s]" because of the shortened "30-day review." *Id.*; *see also* ACAT-ER-016 (noting "the shortened 30-day review period . . . is one of the major benefits of these [E]xemptions as it allows companies to introduce new chemical substances more quickly into commerce.").

Consequently, chemical manufacturers submit hundreds of applications per year to manufacture new chemicals under the Exemptions. *See* EPA, *Exemptions Table*, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/exemptions-table (last updated Oct. 14, 2025) (identifying, in the "Case Number" field, LVE applications with an "L" and LoREX applications with an "X").

Indeed, for fiscal year 2025, applications under the LVE Exemption, alone, outnumber applications under the Standard Review Process. *Compare id.* (identifying 196 LVE applications submitted in FY2025 with "L-25") *with* EPA, *Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs) Table*, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/premanufacture-notices-pmns-and (last updated October 14, 2025) (identifying 154 PMN applications submitted in FY2025 with "P-25").

D. After EPA created the LVE and LoREX Exemptions, it recognized that new PBTs are a category of chemicals that are uniquely risky and difficult to review.

1. In 1999, EPA first established new PBTs as a category of chemicals for conducting premanufacture review. ACAT-ER-260 ("1999 PBT Policy") (establishing "a category of persistent, bioaccumulative, and toxic (PBT) new chemical substances"); *see* 15 U.S.C. § 2625(c) (1976) (authorizing EPA to regulate by "category"). EPA recognized that PBTs were "priority pollutants and potential risks to humans and ecosystems" and that establishing new PBTs as a distinct category "is a major element in the Agency's overall strategy to further reduce risks from PBT pollutants." ACAT-ER-262.

2. Central to the 1999 PBT Policy was a recognition that additional testing was vitally important for new PBTs. First, the Policy contemplated that

applications to manufacture new PBTs would go through the Standard Review Process. *See* ACAT-ER-268-69. After completing that review, EPA would issue orders for new PBTs, requiring additional testing to develop more information about their risks (which is not an option under the Exemptions). *Id.*; *see* 15 U.S.C. § 2604(e) (1976) (authorizing testing). Indeed, new PBTs would be barred from manufacture if they were very persistent and very bioaccumulative—*i.e.* exceeded certain numerical persistence and bioaccumulation criteria. ACAT-ER-268-69. In those cases, companies would be required to submit test data before any manufacture could begin. *Id.* (describing the "Ban Pending Testing" approach).

E. In 2016, Congress overhauled TSCA and strengthened the premanufacture review process for new chemicals.

1. Congress significantly revised the unreasonable risk standard and thereby raised the bar for creating exemption rules and approving exemption applications. First, Congress mandated that EPA consider risks faced by "potentially exposed or susceptible subpopulations"—communities who are more susceptible to exposure to toxic chemicals, such as children, pregnant women, or communities already overburdened by pollution—not just the risks faced by the general population. 15 U.S.C. § 2604(a)(3), (h)(4) (mandating specific consideration of risks to such "potentially exposed or susceptible subpopulation[s]"); *id.* § 2602(12) (defining "potentially exposed or susceptible

subpopulation"); *cf.* 40 C.F.R. § 702.33. EPA has recognized that this definition can cover "[t]ribal communities where reliance on subsistence fishing results in increased chemical exposure via ingestion." 89 Fed. Reg. 37,028, 37,040 (May 3, 2024).

Second, Congress redefined the meaning of unreasonable risk—prohibiting the consideration of "costs and other non-risk factors." *E.g.,* 15 U.S.C. § 2604(a)(3). Assessing the risks posed by new chemicals is now a strictly scientific endeavor.

2. Congress also required EPA to make an affirmative determination on each new chemical application before manufacture could begin, thereby prohibiting the automatic approval of applications where EPA had failed to timely act. *See* 15 U.S.C. § 2604(a)(1)(B)(ii); ACAT-ER-005 (summarizing amendments); *see also* Kevin McLean, Harv. L. Sch., *Three Years After—Where Does Implementation of the Lautenberg Act Stand?* at 19–20 (Feb. 26, 2020), https://eelp.law.harvard.edu/wp-content/uploads/2025/05/McLean-TSCA.pdf. Previously, if EPA did not render a determination within the review period, the application was automatically deemed approved and the applicant could begin manufacturing the new chemical. *See supra* at 17 (citing 15 U.S.C. § 2604(g) (1976)). Consequently, "EPA issued risk determinations for approximately 20% of

new chemical submissions. In 80% of cases, EPA 'dropped' the chemical from further review and allowed it to go to market." EPA, *Statistics for the New Chemicals Program Under TSCA* (Aug. 4, 2025), https://web.archive.org/web/20250812181743/https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-program. Similarly, applications under the LVE and LoREX Exemptions were deemed approved if EPA did not act within the applicable 30-day review period. *See* 40 C.F.R. § 723.50(g)(2) (1995).

Congress put a stop to approvals based on the expiration of the review period, which had undermined the new chemicals review system and endangered public health, allowing manufacturers to commence production of chemicals before EPA had evaluated their risks and decided whether regulation was necessary.

III. The Final Rule Expressly Fast Tracks the Approval of New PBTs under the LVE and LoREX Exemptions for the First Time.

1. In 2023, EPA proposed to amend the regulations governing new chemicals review to "align" the regulations to the 2016 TSCA Amendments. ACAT-ER-234, ACAT-ER-250 ("Proposed Rule"). EPA repeatedly recognized the need to ensure the regulations—including the exemption rules issued under Section

2604(h)(4)—reflect the new requirements to protect "potentially exposed or susceptible subpopulation[s]." *See, e.g.,* ACAT-ER-237.

In light of the 2016 Amendments, EPA recognized a need to modify the LVE and LoREX Exemptions. *See* ACAT-ER-246-49. EPA proposed to end the practice where, if the 30-day review period expired, approval of an application resulted. Under the Proposed Rule, before an applicant could begin manufacture of a new chemical, EPA would be required to make a determination that the chemical complies with the terms of an Exemption. *See* ACAT-ER-258 (third column). EPA also proposed to make the category of PFAS chemicals categorically ineligible for the Exemptions due, in part, to their "longevity and persistence in the environment." ACAT-ER-247; *see also* ACAT-ER-247-49.

2. EPA also recognized the need to restrict the eligibility of new PBTs under the LVE and LoREX Exemptions because PBTs are inherently risky. EPA found that "[w]hen exposure of the environment or biological organisms (including humans) to a PBT chemical is expected, one or more of the conditions above (*i.e.*, serious acute or chronic effects or significant environmental effects) is generally likely to occur, often making the PBT chemical ineligible for the exemptions." ACAT-ER-249.

But EPA took a different approach than what it proposed for PFAS. Instead of proposing to make all new PBTs ineligible for the Exemptions, EPA's proposal would only make a subset ineligible: those new PBTs for which EPA affirmatively determined there would be "anticipated environmental releases and potentially unreasonable exposures." ACAT-ER-258. EPA claimed the newly proposed eligibility criteria reflected long-standing EPA practices that implemented the Agency's 1999 PBT Policy. ACAT-ER-249.

3. Petitioners submitted extensive comments objecting to this proposal. These comments explained that the limits in the LVE and LoREX Exemptions do not protect against the inherent risks posed by PBTs, and therefore, EPA must make new PBTs categorically ineligible for the Exemptions. *See* ACAT-ER-157-60 ("ACAT Comments"); ACAT-ER-225-32 ("EDF Comments"). Furthermore, Petitioners noted that while EPA's proposal referenced the 1999 PBT Policy, it misstated the Policy's scope and effects and failed to codify the core of the Policy: that new PBTs would go through the Standard Review Process and be subject to orders for additional testing. *See* ACAT-ER-231.

Commenters urged EPA to simply make all new PBTs categorically ineligible for expedited approval under the Exemptions and to require new PBTs to be evaluated under the Standard Review Process. ACAT-ER-157-60; ACAT-ER-

225-32. Commenters noted that the 30-day review process for the Exemptions was likely insufficient to carry out a careful, individualized review to assess the risks posed by each new PBT. *See* ACAT-ER-231. Such individualized review is necessary to ensure that EPA does not mistakenly allow the next DDT or PCB onto the market.

4. Largely ignoring these comments, EPA issued the Final Rule, for the first time expressly authorizing the expedited approval of new PBT chemicals under the LVE and LoREX Exemptions. ACAT-ER-029 (Final Rule) (codifying 40 C.F.R. § 723.50(d)(2)(ii)). Under this new Fast-Track Provision, every new PBT is eligible for approval under the Exemptions, unless EPA affirmatively determines that an individual new PBT will result in "anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms." *Id.*

SUMMARY OF ARGUMENT

In promulgating the PBT Fast-Track Provision, 40 C.F.R. § 723.50(d)(2)(ii), EPA violates TSCA. The Provision allows EPA to expedite approval of new PBT chemicals under the LVE and LoREX Exemptions, even though the terms of those Exemptions fail to ensure that the PBT chemicals "will not present an unreasonable risk . . . including . . . to a potentially exposed or susceptible subpopulation." 15 U.S.C. § 2604(h)(4). Circumventing the Standard Review

Process in this manner violates that statutory standard and is arbitrary and capricious.

I.A. In this rulemaking EPA itself recognized that new PBTs are inherently risky and that the terms of the Exemptions—*i.e.* the numerical limits on production (LVE) or releases and exposure (LoREX)—do not sufficiently protect against that risk. Indeed, EPA has never determined that those limitations ensure that the category of new PBT chemicals "will not present an unreasonable risk," as the statute requires. 15 U.S.C. § 2604(h)(4). Accordingly, EPA cannot say that the Exemptions protect subpopulations—like those living at the fenceline of chemical manufacturing plants or Native Alaskans who rely on foods likely to be contaminated by new PBTs—let alone the general population. Thus, in this rulemaking, EPA was required to make new PBTs ineligible for approval under the Exemptions. EPA's refusal to do so violates TSCA and is arbitrary.

I.B. The Fast-Track Provision turns the statute on its head, for the first time affirmatively authorizing the approval of dangerous new PBTs under the Exemptions. Under the Provision, every new PBT is presumptively eligible for expedited approval unless EPA affirmatively determines that a chemical potentially results in unreasonable exposure, which even EPA acknowledges will likely cause serious injury—*i.e.* death, incapacitation, or disfigurement. That violates TSCA

Section 2604(h)(4), which requires EPA to determine, with certainty, that the terms of an exemption rule will prevent such injuries before making a category of chemicals eligible. Instead, the terms of the new Provision now require EPA to prove such injuries will occur in order to reject an application for a new PBT.

I.C. EPA's action is also arbitrary because it is inconsistent with prior EPA precedent where EPA did make a category of new chemicals ineligible for another exemption.

II.A. EPA's justification confirms the arbitrary nature of its action. The Agency claims that the Fast-Track Provision could be used to manage hypothetical PBTs used in closed-loop systems with no releases and no exposures. But this hypothetical is an unsupported fiction: EPA simply ignored evidence that even when used in a closed-loop, new PBTs will eventually have to be disposed of, resulting in some releases and some exposures, which will contaminate the environment and cause injury to people and other organisms. Because of this reality, EPA was unable to identify a single real-world example that matched its zero-release-zero-exposure hypothetical. Moreover, even if this fanciful scenario was not purely hypothetical, the Fast-Track Provision would still not be justified, because the plain text of the Provision authorizes approval of new PBTs with some

exposures. If EPA's goal was to allow for the approval of only zero-release-zero-exposure PBTs, it needed to write a different, narrower provision.

II.B. Finally, EPA claims the Fast-Track Provision codifies the Agency's 1999 PBT Policy, but as Petitioners pointed out in comments, the new Provision conflicts with that policy and EPA failed to respond to those comments.

III. The Court should partially vacate the Fast-Track Provision—excising the language requiring EPA to affirmatively determine that there are "anticipated environmental releases and potentially unreasonable exposures"—and thereby make new PBTs categorically ineligible for approval under the Exemptions. Here, vacatur will ensure that if a company applies to manufacture a new PBT, the chemical will go through the Standard Review Process. In that review, the new PBT will receive individualized scrutiny, individualized regulations tailored to its unique risks, as appropriate, and likely additional ongoing testing. Such individualized review is fully supported by EPA's own findings, and is the default mandate of TSCA.

IV. Doing so would remedy the harm the Fast-Track Provision will inflict on Petitioners and their members, because the Provision threatens them with increased exposure to new PBTs and denies them useful information that EPA would otherwise have to disclose to them.

STANDARD OF REVIEW

TSCA's judicial review provision incorporates the Administrative Procedure Act's standard that requires courts to set aside an EPA action that is "arbitrary, capricious, an abuse of discretion . . . otherwise not in accordance with law[, or] in excess of statutory . . . authority." 5 U.S.C. § 706(2)(A), (C); 15 U.S.C. § 2618. Agency action is arbitrary and capricious when "the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). Judicial review, while "deferential," must be "thorough, probing, [and] in-depth." *Ranchers Cattlemen Action Legal Fund United Stockgrowers of Am. v. U.S. Dep't of Agric.*, 415 F.3d 1078, 1093 (9th Cir. 2005) (citation modified).

ARGUMENT

I. The Final Rule Violates TSCA and Is Arbitrary Because it Fast Tracks the Approval of Inherently Risky New PBTs.

A. EPA's refusal to make PBTs categorically ineligible for the LVE and LoREX Exemptions violates TSCA and is arbitrary.

TSCA requires EPA to make a chemical category ineligible for an exemption where the category may present unreasonable risks of injury even when complying with the terms of the exemption. *See* 15 U.S.C. §§ 2604(h)(4), 2625(c). The record, including EPA's own findings, establishes that the category of new PBTs may—indeed, will likely—present unreasonable risk even when complying with the terms of the LVE and LoREX Exemptions. Thus, EPA was required to make new PBTs categorically ineligible for the Exemptions, and its refusal to do so in the Final Rule is unlawful and arbitrary. *See* ACAT-ER-004 (Final Rule) (making only "certain… PBT… chemical substances . . . ineligible for these [E]xemptions.") (emphasis added).

1. Where the terms of an exemption fail to ensure a category of chemicals "will not present an unreasonable risk," EPA must make the category ineligible for fast-track approval.

1. TSCA authorizes EPA to create a rule exempting new chemicals from the Standard Review Process but only if EPA determines the terms of the exemption rule ensure that chemicals approved under the exemption "will not" present unreasonable risk. 15 U.S.C. § 2604(h)(4); *see* 50 Fed. Reg. at 16,487

("EPA has determined that substances manufactured under the terms of this exemption rule will not present an unreasonable risk." (emphasis added)).[6]

2. If, after EPA has created an exemption, EPA determines that the terms of the exemption no longer ensure that a particular category of chemicals "will not present an unreasonable risk," EPA must make that category ineligible for approval under the exemption. *See* 15 U.S.C. §§ 2604(h)(4), 2625(c). EPA has acknowledged that obligation, stating where "EPA can no longer conclude that [a category of new chemicals] will not present an unreasonable risk to human health or the environment under the terms of [an] exemption rule," EPA must make the category ineligible under the exemption. 75 Fed. Reg. 4,295, 4295 (Jan. 27, 2010) (citation modified) (describing this as "the determination necessary to support an exemption under TSCA [Section 2604(h)(4)]"); *see id.* 4,299–301 ("excluding" a category of polymers from eligibility under a different exemption to the Standard Review Process).

[6] EPA itself also recognized in this rulemaking that "EPA may exempt a chemical substance from section 5 requirements upon application and by rule only if EPA determines the manufacture, processing, distribution in commerce, use, or disposal of the substance will not present an unreasonable risk." ACAT-ER-249.

3. In other words, EPA must make a category of chemicals ineligible for an exemption if chemicals in the category may present unreasonable risk, even when manufactured in compliance with the terms of an exemption.

Unlike other provisions governing the review of new chemicals, the "will-not-present" standard of Section 2604(h)(4) requires certainty. For example, TSCA establishes different standards for different EPA regulatory actions on a new chemical under the Standard Review Process, all of which incorporate uncertainty, including: (1) finding that the information available to EPA is "insufficient to permit a reasoned evaluation of the health . . . effects" of the new chemical; (2) finding that the EPA only has enough information to say a new chemical "may present" unreasonable risk, but not enough information to make a definitive determination; and (3) finding that a chemical is "not likely" to present unreasonable risks. 15 U.S.C. § 2604(a)(3)(B)(i), (ii), (a)(3)(C), (e).

If EPA cannot be certain in advance that the terms of an exemption ensure a category meets the will-not-present standard, the Agency must make the category ineligible. *See Secs. Exch. Comm'n v. McCarthy*, 322 F.3d 650, 656 (9th Cir. 2003) ("It is a well-established canon of statutory interpretation that the use of different words or terms within a statute demonstrates that Congress intended to convey a

different meaning for those words." (citing *Russello v. United States,* 464 U.S. 16, 23 (1983))).

4. When EPA makes a category ineligible under a particular exemption, chemicals in the category can still be approved for manufacture, but they must go through the Standard Review Process (or some other exemption, if eligible). This ensures that each new chemical will receive a "more detailed and comprehensive review and analysis" of the distinct risks posed by the chemical than is possible in the rushed, 30-day exemption review period. ACAT-ER-016. Moreover, under the Standard Review Process, if regulation is necessary, each chemical will receive regulations tailored to their unique risks, rather than simply having to comply with the generic terms of an exemption. Equally important, if EPA finds the risks of the chemical are uncertain, EPA must require more testing, an option that is not available under an exemption. 15 U.S.C. § 2604(e); ACAT-ER-016 (EPA does not "require testing" under its Exemption regulations.).

2. EPA found that the terms of the LVE and LoREX Exemptions do not protect against the inherent risks of new PBTs, but refused to make new PBTs ineligible.

EPA's findings in the Final Rule confirm that the terms of the LVE and LoREX Exemption rules—*i.e.* the numerical limits they place on production volumes and chemical releases—fail to ensure that the category of new PBT

chemicals "will not present an unreasonable risk." 15 U.S.C. § 2604(h)(4). Accordingly, EPA was required to make new PBTs ineligible for approval under those Exemptions. EPA's refusal to do so is unlawful.

1. EPA's own findings and the record, as a whole, establish that new PBTs inherently may present unreasonable risk. By EPA's definition, new PBTs are chemicals that inherently "result[] in potential risks to humans and ecosystems" because such substances persist in the environment, accumulate in organisms, and are toxic—*i.e.* because they are PBTs. *See* 40 C.F.R. § 723.50(b)(12) (emphasis added). EPA also found that "[w]hen exposure of the environment or biological organisms (including humans) to a PBT chemical is expected . . . serious acute or chronic effects or significant environmental effects . . . [are] generally likely to occur." ACAT-ER-249 (emphasis added).

EPA concluded that new PBTs "are of special concern" because "their persistence and bioaccumulation potential, coupled with toxicity concerns, can result in risk to biological systems." ACAT-ER-248 (emphasis added). Those potential risks and likely serious or significant effects mean that new PBTs inherently may present unreasonable risk.

2. The terms of the Exemptions do not protect against those inherent risks—*i.e.* they fail to ensure that new PBTs "will not present an unreasonable

risk" as TSCA requires. 15 U.S.C. § 2604(h)(4). The LVE and LoREX Exemptions authorize the manufacture of chemicals either where: (1) production quantities are below 10,000 kilogram per year, 40 C.F.R. § 723.50(c)(1) (the LVE); or (2) releases of the chemical into the environment and exposures are below certain thresholds (*e.g.* no incinerator releases above 1 microgram per cubic meter maximum annual average concentration), 40 C.F.R. § 723.50(c)(2) (the LoREX).

Those limitations on production and exposure fail to ensure that new PBTs "will not present an unreasonable risk" including to "potentially exposed or susceptible subpopulation[s]." 15 U.S.C. § 2604(h)(4). When EPA established and updated the Exemptions in 1985 and 1995, the Agency did not analyze whether the Exemptions' numeric thresholds protected people or the environment from PBTs. *See, e.g.,* 60 Fed. Reg. at 16,336 (absence of any discussion of PBTs); 50 Fed. Reg. at 16,477 (similar). The Agency could not have been expected to do so because EPA did not even identify new PBTs as a distinct chemical category until 1999. *See* ACAT-ER-260 (1999 PBT Policy).

Similarly, EPA never analyzed whether the terms of the LVE and LoREX Exemptions protect relevant subpopulations—like children, Native Alaskans who rely on traditional foods, or communities at the fenceline of chemical plants. The obligation to protect such subpopulations was only established by Congress in the

2016 Amendments, long after the Exemptions were established. *Compare* 15 U.S.C. § 2604(h)(4) (requiring protection of subpopulations) *with id.* § 2604(h)(4) (1976) (no such requirement).

In other words, EPA has never analyzed and determined that the LVE's 10,000 kilogram production limit protects a community from a new PBT manufactured at a nearby plant. Similarly, EPA has never analyzed or determined that the LoREX's limits on consumer, worker, and general population exposures protect a Native Alaskan from eating fish or whale contaminated by dangerous levels of a new PBT. Indeed, EPA has never analyzed these limits with respect to PBTs at all.

And in the challenged rulemaking, EPA conducted no analysis to remedy these deficiencies.

3. Accordingly, in the Final Rule, EPA was required to make new PBTs ineligible for approval under the Exemptions because the Agency could not (and did not) determine that communities and the environment would be safe if new PBTs were manufactured under the terms of the Exemptions. *See* 15 U.S.C. § 2604(h)(4). Doing so was necessary to achieve EPA's stated goal "to align the regulatory text" of the Exemptions "with the amendments to TSCA's new

chemicals review provisions" and with the Agency's own findings about the inherent risks of PBTs. ACAT-ER-234; *see also* ACAT-ER-248-49.

EPA itself recognized the need to limit the eligibility of new PBTs under the Exemptions. For example, EPA noted that the existing Exemption terms "do not expressly disqualify" the category of new PBTs, despite the fact that new PBTs "often" may present unreasonable risks. ACAT-ER-249; *see also id.* ("EPA's specific concerns for PBT chemicals as they relate to [the Exemptions] are not separately codified in the existing regulations.").

4. EPA's refusal to make PBTs categorically ineligible violates TSCA, 15 U.S.C. § 2604(h)(4), and is arbitrary and capricious, *see State Farm*, 463 U.S. at 43 (an action is arbitrary if there is not a "rational connection between the facts found and the choice made") (citation modified).

B. The Fast-Track Provision affirmatively authorizes the approval of new PBTs under the LVE and LoREX Exemptions without safeguarding health or the environment, which violates TSCA and is arbitrary.

1. The Fast-Track Provision requires EPA to prove a new PBT is unsafe to be ineligible for the Exemptions, which violates the will-not-present standard.

The terms of the Fast-Track Provision turn the statute on its head, making each and every new PBT eligible for expedited review under the Exemptions unless EPA affirmatively determines that a specific PBT is unsafe. In effect, the

rule treats an absence of evidence as a reason to expedite the approval of a new PBT chemical, rather than a reason to deny an exemption application and require the new PBT to go through the Standard Review Process.

1. By its plain terms, the Fast-Track Provision greenlights the approval of any new PBT under the Exemptions, unless EPA makes an affirmative determination that a specific PBT is associated with both "anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms." 40 C.F.R. § 723.50(d)(2)(ii) (emphasis added). Unless EPA makes both findings, a new PBT "can[] be manufactured" under either Exemption. *Id.* § 723.50(d). Thus, if EPA lacks exposure or release information that would allow it to make these twin determinations—as is often the case for novel new PBTs that are not currently manufactured or in use—a new PBT would be eligible under the Fast-Track Provision.

In effect, the rule treats an absence of evidence on releases and exposures as a reason to approve an exemption for a new PBT chemical, rather than a reason to deny the application. Given that new PBTs may present unreasonable risk—even when meeting the Exemptions' limits on production or release and exposure—requiring EPA to make these additional affirmative findings violates TSCA's will-not-present standard. 15 U.S.C. § 2604(h)(4). On this record, EPA was required to

make new PBTs categorically ineligible for the Exemptions, without the need for any further affirmative findings.

2. Moreover, requiring EPA to determine that there are releases and exposures is tantamount to requiring EPA to determine that a new PBT likely presents unreasonable risk. This is because, as EPA acknowledged, if there are "exposure[s]" to a PBT chemical, "serious acute or chronic effects or significant environmental effects [are] generally likely to occur"—such as "death, severe or prolonged incapacitation, [or] disfigurement." ACAT-ER-249 (emphasis added); 40 C.F.R. § 723.50(b)(6)–(8) (defining "serious acute," "serious chronic," and "significant environmental" effects). In other words, the Fast-Track Provision establishes that a new PBT is only ineligible for expedited review if EPA affirmatively determines the chemical "likely" presents an unreasonable risk of injury. ACAT-ER-249. Every other new PBT is eligible for the Exemptions.

That is the precise opposite of what TSCA demands. Instead of requiring EPA to determine, with certainty, that a new PBT is safe (*i.e.* "will not present an unreasonable risk") before granting an Exemption application, the terms of the Provision require EPA to prove that a new PBT is unsafe in order to reject it. 15 U.S.C. § 2604(h)(4).

2. The Fast-Track Provision hinges on a nonsensical "unreasonable exposure" standard, which is arbitrary.

1. The Fast-Track Provision ties exemption eligibility to whether there are "potentially unreasonable exposures" to a new PBT, 40 C.F.R. § 723.50(d)(2)(ii), but that neologism "is nonsensical" within the context of TSCA. *Idaho Power Co. v. Fed. Energy Reg. Comm'n*, 312 F.3d 454, 461 (D.C. Cir. 2002), as amended on reh'g (Mar. 5, 2003).

Under TSCA, whether an exemption can be granted is based on "risk," which is a function of hazard and exposure. 15 U.S.C. § 2604(h)(4); 60 Fed. Reg. at 16,345 ("Risk is the combination of the hazard presented by a chemical substance or category of chemical substances and the exposure of humans or the environment to the substances or category.") Thus, to determine risk to people, the Agency must compare (1) the estimated amount of the chemical people take in through air, water, etc. (exposure) with (2) scientific information about the harms the chemical causes and the dose at which the chemical causes harm (hazard). *See* 60 Fed. Reg. at 16,345. By integrating these two assessments to see whether the level of exposure exceeds the dose that causes harm, the Agency determines whether there is risk of injury.

Under this statutory framework, the concept of an "unreasonable exposure" is nonsensical because it only assesses one element of risk, exposure, while

ignoring the other, hazard. Ingesting one liter of water and one liter of gin will have vastly different effects even though the exposure is the same, because they have different hazards. It would be nonsensical to refer to ingesting one liter of liquid as either a reasonable or an unreasonable exposure without specifying the liquid. So too for new PBTs.

2. To the extent the Fast-Track Provision uses "unreasonable exposure" as shorthand to mean that EPA will assess the potential exposures of each new PBT and compare those exposures to the PBT's potential hazard, the Provision fares no better. In that case, by comparing hazard and exposure, EPA is assessing risk, and "unreasonable exposure" is just a euphemism for "unreasonable risk." And under that reading, the Fast-Track Provision makes new PBTs ineligible only if EPA affirmatively determines they have "potentially unreasonable exposures"—*i.e.* potentially unreasonable risks. 40 C.F.R § 723.50(d)(2)(ii). That would violate TSCA's will-not-present standard, which instead requires that EPA prove a new chemical is safe before approving it under an exemption, not find it is unsafe as a prerequisite for rejecting it. 15 U.S.C. § 2604(h)(4).

3. Commenters raised these very points, yet EPA did not acknowledge them, let alone respond, rendering the rule arbitrary and capricious. ACAT-ER-231-32 (EDF Comments) (raising issue); ACAT-ER-120-25 ("Response to

Comments") (failing to respond); *see Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015) ("An agency must consider and respond to significant comments."); *also Ohio v. EPA*, 603 U.S. 279, 293–94 (2024) (An agency that offers "no reasoned response" to comments "fail[s] to supply a satisfactory explanation," and thereby, acts arbitrarily. (citation modified)).

C. The Fast-Track Provision contravenes EPA's prior precedents and practices, which is arbitrary.

Finally, the Fast-Track Provision is arbitrary because it "fails to follow [EPA's] own precedent [and] fails to give a sufficient explanation for failing to do so." *Andrzejewski v. Fed. Aviation Admin.*, 563 F.3d 796, 799 (9th Cir. 2009); *Kentucky Mun. Energy Agency v. Fed. Energy Reg. Comm'n*, 45 F.4th 162, 178 (D.C. Cir. 2022) (similar).

The Fast-Track Provision contradicts EPA's prior precedent making a category of chemicals ineligible for exemptions based on the fact that the category is persistent, bioaccumulative, and toxic. In 2010, EPA made a category of "polymers containing PFAS or PFAC" ineligible for an exemption based on EPA's expectation that this category would degrade and release residual chemicals that would "persist in the environment, may bioaccumulate, and may be highly toxic"—*i.e.* may be PBTs. 75 Fed. Reg. at 4,296. Given that finding, EPA determined it could "no longer make the determination that . . . [the category] 'will

not present an unreasonable risk'" and therefore made the entire category ineligible for the exemption. *Id.* (quoting 15 U.S.C. § 2604(h)(4)).

EPA departs from that prior precedent here by maintaining the eligibility of new PBTs under the Exemptions, despite EPA's conclusions that: (1) they are inherently risky because they are persistent, bioaccumulative, and toxic; and (2) the terms of the Exemptions do not sufficiently protect against those inherent risks. EPA did not recognize nor explain why it was departing from its prior precedent, which is arbitrary. *Andrzejewski*, 563 F.3d at 799; *see* ACAT-ER-120-25 (Response to Comments) (absence).

II. EPA's Explanations for Promulgating the Fast-Track Provision Confirm that its Action Is Arbitrary.

A. Unsupported speculation about possible zero-release-zero-exposure PBTs cannot justify the Fast-Track Provision, which authorizes approval of PBTs with some exposure.

EPA argues that PBTs should be eligible under the Exemptions because there may be some hypothetical PBTs for which there are no releases and no exposures. Specifically, EPA speculates "that there are instances where PBT chemical substances can be managed under [the LVE or LoREX] exemption[s]" because the chemical "will not result in worker, general population, or consumer exposure and . . . is not expected to result in releases to the environment." ACAT-ER-017 (Final Rule).

That explanation fails. First, EPA offers no evidence that there are PBT chemicals that do not release to the environment or do not cause exposure. Second, even if there were such zero-release-zero-exposure PBTs, the plain terms of the Fast-Track Provision sweep far broader than EPA's purported justification, making new PBTs eligible even if they result in some exposure. Thus, EPA has failed to make "a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43 (citation modified).

1. EPA's claim—that some PBTs can be manufactured, processed, distributed in commerce, used in products, and ultimately disposed but then never release to the environment or cause human exposure—is fanciful.

EPA simply had no response to Petitioner's comments that new PBTs will eventually be released into the environment, cause exposures, and thereby result in serious injury. ACAT-ER-120-25 (Response to Comments) (absence); *see Ohio*, 603 U.S. at 293 (An agency that offers "no reasoned response" to comments acts arbitrarily.). Petitioner's comments demonstrated that, according to the best available science, releases of a new PBT are inevitable and once a PBT is released, exposures will result. *See* ACAT-ER-158-60 (ACAT Comments) (summarizing "ample evidence that PBT chemicals release into the environment at some point under the conditions of use."). These comments noted that all chemicals eventually

have to be disposed; thus, "when products containing PBTs are disposed of . . . they cause significant environmental releases." *See* ACAT-ER-159. Given EPA's acknowledgment in the proposed rule that releases result in exposures and that exposures result in "'serious'" injury, the comments argued serious injury was inevitable. ACAT-ER-159-60 (quoting 88 Fed. Reg. at 34,114–15).

EPA did not acknowledge or respond to the scientific evidence presented about the inherent likelihood that PBTs will be released and cause exposure. *See* ACAT-ER-120-25 (Response to Comments) (absence). Instead, EPA baldly asserted that there are PBTs that do not result in releases and exposure. ACAT-ER-122. "EPA's response does not meaningfully address [these] comment[s]," and its action is therefore arbitrary. *Nat'l Parks Conservation Ass'n v. EPA*, 788 F.3d 1134, 1146 (9th Cir. 2015); *see State v. Biden*, 10 F.4th 538, 556 (5th Cir. 2021) ("Nodding to concerns raised by commenters only to dismiss them in a conclusory manner is not a hallmark of reasoned decisionmaking." (citation modified)).

Indeed, EPA failed to identify a single real-world example of a PBT for which there are no releases and exposures; such "speculation" is arbitrary. *Sinclair Wyoming Refining Company LLC v. EPA*, 114 F.4th 693, 713–14 (D.C. Cir. 2024) (finding EPA action arbitrary when the Agency provided "no studies or data" but rested on "sheer speculation" (citation modified)).

2. Even if such zero-release-zero-exposure PBTs exist, EPA's justification fails on its own terms because the Fast-Track Provision plainly authorizes the approval of PBTs with some exposures, so long as the exposures are not "unreasonable." 40 C.F.R. § 723.50(d)(2)(ii). The disconnect between the "agency's explanation" for the Provision and what it "actually does" is arbitrary. *EDF v. EPA*, 922 F.3d 446, 454 (D.C. Cir. 2019) (citing *State Farm*); *Goldstein v. Secs. and Esch. Comm'n*, 451 F.3d 873, 882–83 (D.C. Cir. 2006) (noting that a broad regulation was based on an agency "conclusion [that] does not follow from its premise" and that the rule should be "tailored" to the premise).

If EPA intended to limit the eligibility under the Fast-Track Provision to zero-release-zero-exposure PBTs, it could have codified that limitation. Instead, the Provision goes "beyond what the [Agency's] justification supported—raising doubts about whether the solution lacks a rational connection to the problem described." *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania,* 591 U.S. 657, 708 (2020) (Kagan, J., concurring) (citation modified). Here, "the rule's overbreadth causes serious harm" and is arbitrary. *Id.*

B. The Fast-Track Provision's focus on "unreasonable exposures" does not codify and is inconsistent with the Agency's 1999 PBT Policy.

EPA also seeks to justify the Fast-Track Provision by arguing that it merely "codif[ies] EPA's long-standing practice" of rejecting Exemption applications for new PBTs with "anticipated environmental releases and potentially unreasonable exposures," which EPA claims reflects its 1999 PBT Policy. ACAT-ER-249 (Proposed Rule) (section "Codifying EPA's Policy Concerning PBT Chemicals"); ACAT-ER-017 (Final Rule) (similar).

1. That explanation is arbitrary because it fails to respond to Petitioner's comments pointing out that there was no such long-standing practice and that the Fast-Track Provision is inconsistent with the 1999 PBT Policy. *See Ohio*, 603 U.S. at 293. Petitioner's comments noted that the Policy made no mention of "unreasonable exposures," let alone suggested that new PBTs without "unreasonable exposure[s]" were eligible for the Exemptions. ACAT-ER-227, ACAT-ER-229 (EDF Comments).

Instead, the 1999 PBT Policy contemplated that new PBTs would go through the Standard Review Process and thus made no mention of the LVE or LoREX Exemptions. ACAT-ER-226-29 (EDF Comments); *see* ACAT-ER-268-69 (1999 PBT Policy). Additionally, the Policy contemplated that EPA would

typically order limits on new PBTs—particularly new testing of the chemical—reflecting that EPA lacked information to accurately determine their risk. *See* ACAT-ER-268-69; *see also* ACAT-ER-264 (discussing EPA's testing authority under Section 5(e)—*i.e.* 15 U.S.C. § 2604(e)). Indeed, for very persistent, very bioaccumulative new PBTs, the Policy contemplated that EPA would require testing to be completed before manufacture could begin. ACAT-ER-268-69; *see* ACAT-ER-228-29 (discussing the Policy's "Ban Pending Testing" approach).

Moreover, Petitioner's comments noted that EPA categorically rejected all LVE applications for all new PBTs for a period of several years, undermining EPA's claim of a long-standing approach. ACAT-ER-226 (n. 120). The comment asked EPA to codify the 1999 PBT Policy in the updated regulations, thereby making new PBTs categorically ineligible for the Exemptions. ACAT-ER-225-32.

EPA offered no response, simply reiterating its incorrect position that its new Fast-Track Provision codifies EPA's preexisting policy. *See* ACAT-ER-017 (Final Rule); ACAT-ER-120-25 (Response to Comments) (failing to respond). That failure to respond to Petitioner's comments is arbitrary. *Ohio*, 603 U.S. at 293–95.

2. EPA's departure from the actual 1999 PBT Policy is also arbitrary and capricious because it is unexplained. EPA erroneously claimed the Fast-Track

Provision codifies the 1999 PBT Policy and thus failed to "display awareness that it [was] changing position" from its Policy. *California Pub. Utilities Comm'n v. Fed. Energy Reg. Comm'n*, 879 F.3d 966, 977 (9th Cir. 2018) (citation modified) (holding agency action arbitrary where it departed from a "longstanding policy . . . without acknowledgement or explanation").

III. The Court Should Vacate the Unlawful Language in the Fast-Track Provision that Makes New PBTs Eligible for the Exemptions.

1. The Court should vacate the unlawful portion of the Final Rule to ensure that new PBTs are categorically ineligible for approval under the LVE and LoREX Exemptions, thereby ensuring EPA's regulations satisfy the will-not-present standard of Section 2604(h)(4). Specifically, the Court should vacate the text stricken below:

> A new chemical substance cannot be manufactured under this section, notwithstanding satisfaction of the criterion of paragraph (c)(1) or (2) of this section, if EPA determines, in accordance with paragraph (g) of this section, that the substance . . . is… A PBT chemical substance ~~with anticipated environmental releases and potentially unreasonable exposures to humans or environmental organisms.~~

ACAT-ER-029 (Final Rule) (codifying the Fast-Track Provision at 40 C.F.R. § 723.50(d)(2)(ii)).

2. Partially vacating the Provision in this manner is appropriate because when faced with invalid regulations courts should "try to limit the solution to the

problem." *See Nat. Res. Def. Council v. Wheeler*, 955 F.3d 68, 81–82 (D.C. Cir. 2020) (quoting *Ayotte v. Planned Parenthood of N. New England*, 546 U.S. 320, 328–29 (2006)); *Finnbin, LLC v. Consumer Prod. Safety Comm'n*, 45 F.4th 127, 136 (D.C. Cir. 2022) (stating that partial vacatur is presumptively the appropriate remedy when only one aspect of a rule is challenged).

Here, EPA recognized that it needed to restrict the LVE and LoREX exemptions to protect against the inherent risks posed by new PBTs to comply with the amended TSCA. ACAT-ER-017 (Final Rule); *see also* ACAT-ER-248-49 (Proposed Rule). Striking the unlawful fast-track language achieves that goal. And partial vacatur is fully supported by the record, in which EPA has acknowledged the unreasonable risks associated with PBT releases and exposures.

Partial vacatur is supported by ordinary severability principles and EPA's expressed preference for severability of the Final Rule. *See Cmty. for Creative Non-Violence v. Turner*, 893 F.2d 1387, 1394 (D.C. Cir. 1990) (Noting that a court's "presumption [regarding a regulation] is always in favor of severability."); ACAT-ER-018 (stating the Final Rule is severable). And partial vacatur is preferable to full vacatur of the entirety of the Provision, 40 C.F.R. § 723.50(d)(2)(ii), because "there is no reason to think that [EPA] . . . would have

preferred no new rules at all" given EPA's recognition of the need to limit the eligibility of PBTs. *Finnbin,* 45 F.4th at 136; *see* ACAT-ER-248-49.

3. Partially vacating the Fast-Track Provision would not prohibit the manufacture of new PBTs, but rather would require applicants seeking to make a new PBT chemical to apply through the Standard Review Process. The Standard Review Process would ensure that each new PBT receives: individualized scrutiny of its risks; regulations tailored to any specific unreasonable risks found; and, if EPA needs more information on the chemical, a requirement for testing.

4. If this Court disagrees that vacatur is the appropriate remedy, remand of the Provision back to EPA for reconsideration per the Court's ruling would be an appropriate alternative remedy. *A Cmty. Voice v. EPA*, 997 F.3d 983, 988 (9th Cir. 2021) (remanding, without vacatur, an insufficiently protective TSCA rule).

IV. Petitioners Have Standing.

Petitioners have associational standing to challenge the Fast-Track Provision on behalf of their members and the individual supporters whom Petitioners represent. *See Am. Unites for Kids v. Rousseau*, 985 F.3d 1075, 1096–97 (9th Cir. 2021). Petitioners also have standing based on informational injuries caused by the rule. *Animal Legal Def. Fund v. United States Dep't of Agric.*, 935 F.3d 858, 865–68 (9th Cir. 2019).

1. Petitioners' members and the people they represent are harmed by the manufacture, processing, distribution, use, and disposal of new PBT chemicals. ACAT serves and has members who are Native Alaskans whose way of life is being threatened by the cumulative exposure of Arctic wildlife to PBT chemicals. *See* Miller Decl. ¶¶ 3–6, 11–18. These individuals fish, hunt, and gather traditional foods—like fish or whale—and therefore will be exposed to new PBTs that will migrate to the arctic and contaminate their traditional foods. *Id*. ¶¶ 12–16, 18; Waghiyi Decl. ¶¶ 8–18; Jemewouk Decl. ¶ 4. Similarly, EDF's members are likely to be exposed to new PBTs as a result of the Fast-Track Provision in light of the fact that EPA has recently approved the manufacture of such new PBTs near their homes and workplaces. *See generally* Anglin Decl.; Deferrante Decl.; Vultaggio Decl.; *also* Doa Decl. ¶¶ 39–41.

As individuals within overburdened Native Alaskan communities and fenceline communities, ACAT's and EDF's members are "a potentially exposed or susceptible subpopulation," which Congress required EPA to take special care to protect from exposure to new chemicals. 15 U.S.C. §§ 2602(12), 2604(h)(4).

2. These individuals face a "credible threat" from the PBT Fast-Track Provision because it weakens the standards designed to protect them from new PBTs. *Nat. Res. Def. Council v. EPA*, 735 F.3d 873, 879 (9th Cir. 2013); *Ass'n of*

Irritated Residents v. EPA, 10 F.4th 937, 943 (9th Cir. 2021); *see also Safer Chems., Healthy Fams. v. EPA*, 943 F.3d 397, 421 (9th Cir. 2019) (finding standing to challenge regulation that arguably "threatens [petitioners'] concrete interest in the health protections provided by TSCA").

3. Petitioners and their members are also harmed because the Fast-Track Provision denies them information on new PBTs that EPA would have been required to disclose if the chemicals were ineligible for the Exemptions and instead subject to the Standard Review Process. *Animal Legal Def. Fund*, 935 F.3d at 867 ("A plaintiff sustains a cognizable informational injury in fact when agency action cuts her off from information which must be publicly disclosed pursuant to a statute." (citation modified)).

TSCA mandates that EPA disclose information on a new PBT that is submitted or generated during the Standard Review Process. *See* 15 U.S.C. § 2604(b)(3), (d)(1). And if EPA had codified the 1999 PBT Policy, companies seeking to manufacture new PBTs ordinarily would be required to develop additional test data that EPA would be required to publicly disclose. *Id.* § 2604(b)(3), (e); *see supra* at 22–23 (describing testing obligations under 1999 PBT Policy). This information would be helpful to Petitioners' "advocacy, which often involves presenting scientific data about chemicals to regulatory bodies at the

state and federal level," Miller Decl. ¶ 25, and would help Petitioners' members remain informed about the risks associated with new chemicals entering their environment, Waghiyi Decl. ¶¶ 7, 20. *See also* Doa Decl. ¶¶ 43, 44 (describing informational injuries to EDF).

4. This Court can remedy those harms by vacating the unlawful portions of the Fast-Track Provision or remanding the Provision back to the Agency to reconsider its unlawful action. *See, e.g., Nat. Res. Def. Council*, 735 F.3d at 873 (finding standing and vacating rule); *Nw. Requirements Utilities v. Fed. Energy Reg. Comm'n*, 798 F.3d 796, 807 n. 8 (9th Cir. 2015) (holding an injury is redressable by remand back to the agency to reconsider even if the agency may decide not to alter course after remand).

CONCLUSION

For the foregoing reasons, Petitioners respectfully request that the Court declare the PBT Fast-Track Provision unlawful and partially vacate the portions of the Provision that make PBTs ineligible for the LVE and LoREX Exemptions only on a determination of "anticipated environmental releases and potentially unreasonable exposures." 40 C.F.R. § 723.50(d)(2)(ii).

Respectfully submitted this 17th day of October, 2025.

/s/ *Michael Youhana*

Michael Youhana
Earthjustice
48 Wall St., 15th Floor
New York, NY 10005
(212) 284-8033
myouhana@earthjustice.org

Tosh Sagar
Earthjustice
1001 G St NW
Suite 1000
Washington DC 20001
(202) 667-4500
tsagar@earthjustice.org

Counsel for Alaska Community Action on Toxics

/s/ Samantha Liskow
Samantha Liskow
Environmental Defense Fund
257 Park Ave S
New York, NY 10010
(212) 616-1247
sliskow@edf.org

Counsel for Environmental Defense Fund

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 8. Certificate of Compliance for Briefs

Instructions for this form: http://www.ca9.uscourts.gov/forms/form08instructions.pdf

9th Cir. Case Number(s) 25-158, 25-572, 25-573

I am the attorney or self-represented party.

This brief contains 11,599 **words,** including 37 words manually counted in any visual images, and excluding the items exempted by FRAP 32(f). The brief's type size and typeface comply with FRAP 32(a)(5) and (6).

I certify that this brief *(select only one)*:

- ○ complies with the word limit of Cir. R. 32-1.
- ○ is a **cross-appeal** brief and complies with the word limit of Cir. R. 28.1-1.
- ○ is an **amicus** brief and complies with the word limit of FRAP 29(a)(5), Cir. R. 29-2(c)(2), or Cir. R. 29-2(c)(3).
- ○ is for a **death penalty** case and complies with the word limit of Cir. R. 32-4.
- ○ complies with the longer length limit permitted by Cir. R. 32-2(b) because *(select only one)*:
  - ☐ it is a joint brief submitted by separately represented parties.
  - ☐ a party or parties are filing a single brief in response to multiple briefs.
  - ☐ a party or parties are filing a single brief in response to a longer joint brief.
- ◉ complies with the length limit designated by court order dated 07/03/2025.
- ○ is accompanied by a motion to file a longer brief pursuant to Cir. R. 32-2(a).

Signature s/Michael Youhana **Date** 10/17/2025
*(use "*s/[typed name]*" to sign electronically-filed documents)*